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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,649	10/07/2003	Robert A. Holton	FSUM 10442.19	5089

321 7590 11/09/2004

SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
DELACROIX MUIRHEI, CYBILLE	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/680,649	HOLTON, ROBERT A.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

1. Claims 1-17 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable Broder et al., 6,395,770 B1 and McChesney-Harris, US 2001/0029264 A1 in view of Goodman & Gilman's, The Pharmacoloqical Basis of Therapeutics, Ninth Edition.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New claims 18-20 fall under the rejection of claims 1-17 given previously in the office action mailed March 23, 2004. Remarks concerning these claims will be made in the comments, which follow.

Response to Amendment(s)

The following is responsive to Applicant's amendment received July 23, 2004.

No claims are cancelled. Claims 18-20 are added. Claims 1-20 are currently pending.

The previous claim rejection under 35 USC 112, first paragraph, set forth in paragraph 1 of the office action mailed March 23, 2004, **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 112, second paragraph, set forth in paragraphs 2-4 of the office action mailed March 23, 2004, **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous claim rejection under 35 USC 103(a) (please see paragraph 1 above), set forth in paragraphs 4-5 of the office

action mailed March 23, 2004, have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed March 23, 2004 with the following additional comment:

Applicant submits that, as amended herewith, claim 1 is directed to a method of treating a patient afflicted with a cancer selected from the group consisting of breast, head, neck, esophageal, lung, and colon cancer by **orally** administering a pharmaceutical composition consisting essentially of a taxane, a solvent capable of dissolving the taxane, polyoxyethylatated castor oil, a diluent, and optionally a flavoring, **wherein the taxane has a solubility in ethanol at room temperature of at least 200 mg/ml**. Therefore, the method of claim 1 requires use of a taxane having a solubility in ethanol at room temperature of at least 200 mg/ml.

In contrast, Broder et al. and McChesney-Harris merely disclose formulations containing taxol (also known as paclitaxel). Taxol, however, does not have a solubility of ethanol of at least 200 mg/ml; rather, the solubility of taxol in ethanol is less than 40 mg/ml. Furthermore, Broder et al., McChesney-Harris, and Goodman and Gillman do not suggest that any advantages could be derived by selecting a taxane having a solubility in ethanol which is substantially greater than the solubility of taxol in ethanol.

Said arguments have been carefully considered but are not found to be persuasive.

It appears from Applicant's arguments that Broder and McChesney-Harris' disclosure of oral formulations containing taxol or paclitaxel falls outside the scope of

the claimed method since the solubility of taxol in ethanol is less than 40 mg/ml. However, both Broder and McChesney-Harris disclose oral formulations containing taxanes other than paclitaxel. In other words, the Broder and McChesney-Harris patents are not directed solely to the use of oral formulations containing paclitaxel. Broder et al. teach oral administration of the « taxane class of antineoplastic agents, in particular paclitaxel and its derivatives, analogs and prodrugs, and the semisynthetic paclitaxel analog docetaxel" (please see col. 6, lines 23-28). Please see also col. 7, lines 20-26, where Broder et al. disclose that the class of orally administered therapeutic agents are paclitaxel, other taxanes, docetaxel and derivatives and prodrugs of all of the foregoing, particularly their 2'-MPM salts and other 2'-methylpyridinium salts.

McChesney-Harris discloses novel methods and compositions for delivery of paclitaxel and other derivatives or their water insoluble derivatives (please see [0009]. Thus, the Examiner respectfully submits that, absent evidence to the contrary, the disclosed taxanes and water insoluble derivatives (other than paclitaxel) would obviously, if not inherently, exhibit the claimed solubility in ethanol, i.e. at least 200 mg/ml. Applicant has not distinguished the taxane class of drugs disclosed in the prior art from the taxanes claimed in the instant application. Paclitaxel may fall outside the scope of the claims; however, applicant's arguments directed only to paclitaxel do not remove the entire class of taxanes taught by the prior art from the scope of the claimed invention.

Finally, Applicant's remark that the prior art of record does not suggest that any advantages could be derived by selecting a taxane having a solubility in ethanol which

is substantially greater than the solubility of taxol in ethanol is noted. However, the Examiner respectfully disagrees. Since the prior art recognizes the problem of limited solubility of taxanes, the Examiner respectfully maintains that it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the oral compositions used in the methods of Broder et al. and McChesney-Harris such that the taxane has sufficient solubility necessary to render the oral composition therapeutically effective. Absent evidence to the contrary, such a modification would have been motivated by the reasonable expectation of producing an oral composition which when orally administered is readily bioavailable.

Finally, concerning claims 18-20, McChesney-Harris teaches in claim 26, that breast cancer may be treated using the taxane-containing compositions. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat colon or esophagus cancer using the disclosed oral taxane compositions because, absent evidence to the contrary, one of ordinary skill in the art would reasonably expect the anti-neoplastic properties of the taxane compositions to demonstrate cytotoxicity against cancer of the colon or esophagus.

Conclusion

Claims 1-20 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Nov. 3, 2004